EXHIBIT G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: Elysium Health-ChromaDex Litigation	Case No. 1:17-cv-07394 (LJL)

EXPERT REPORT OF STEVEN M. WEISMAN, PH.D.

March 4, 2021
Date

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I. INTRODUCTION

I, Steven M. Weisman, have been retained as an expert by LTL Attorneys, LLP, counsel on behalf of ChromaDex, Inc. ("ChromaDex"), to provide opinions and offer testimony in this case regarding FDA regulation of dietary supplements—specifically regulations governing New Dietary Ingredients ("NDI"), the criteria for identifying substances as Generally Recognized as Safe ("GRAS"), and Current Good Manufacturing Practices ("CGMPs")—as well as the regulatory pathways taken by NIAGEN® and Basis. My opinion is based on consideration of ChromaDex's NDI notifications ("NDINs") and GRAS dossiers, Elysium's GRAS dossiers, as well as other materials and regulations, which are listed in **Exhibit 2** attached hereto, and my general knowledge and experience in the field of regulatory affairs. If called upon to testify in court, I will use presentations and other materials to illustrate my analysis set forth in this report and the attached exhibits.

My opinions and conclusions are based on the most current information made available to me as of the date of this report. I reserve the right, within the Court's guidelines, to modify, amend, or supplement my opinions in view of the evidence and testimony that Elysium or its experts may present, or based on any additional discovery, including third-party discovery, or other information provided to me or found by me in this matter. I further reserve the right to respond to issues raised by any other party if asked to do so by the Court or counsel.

II. QUALIFICATIONS AND COMPENSATION

My full curriculum vitae, along with a list of my publications authored in the previous ten years and a list of all other cases in which I have testified as an expert at trial or by deposition during the previous four years, is attached as **Exhibit 1**. A brief summary of my qualifications is set forth below.

A. Education

I received my Ph.D. in Pharmacology from the Cornell University Graduate School of Medical Sciences and post-doctoral training in Immunopharmacology from the Roche Institute of Molecular Biology. I am trained as a clinical pharmacologist with 30 years of experience supporting pharmaceutical and medical device product development activities in a variety of areas, including regulatory strategy, regulatory submissions, product development plans, product communication strategies, and preclinical and clinical testing programs.

B. Employment History

I am the President and CEO of Innovative Science Solutions, Inc., where I provide scientific consulting services for numerous healthcare product companies.

I have served as Global Director of Medical and Clinical Affairs at Bayer Corporation, Director of Strategic Research at Sterling Winthrop Inc., and held similar positions at Hoffman La Roche and Procter & Gamble. In these positions, I have overseen the development of a large number of healthcare products. Through this work, I have developed direct experience related to the actions sponsors must take to obtain approval from the Food and Drug Administration (FDA) and to bring products to the market.

In my consultant role, I guide many companies, big and small, in developing regulated and unregulated healthcare products to ensure those products' compliance with FDA and all other applicable regulations. Over my years as a consultant, I have been called upon to develop regulatory strategies, product development plans, preclinical and clinical testing programs, regulatory submissions, and product defense/communication strategies for drugs, foods, cosmetics, and dietary supplements. I also manage the preparation of FDA regulatory submissions, including NDI and GRAS notifications.

In addition to my work advising companies on their product development efforts, I have been asked to testify before the FDA, Federal Trade Commission (FTC), and other regulatory bodies around the world. I have organized and presented at numerous symposia, FDA advisory committee meetings, and other regulatory venues. I have provided expert testimony in a number of previous legal cases.

C. Publications

I have authored many scientific articles that have been published in peer-reviewed journals that call upon my scientific, study design, statistical, and interpretive knowledge. Over the course of my scientific career, I have published dozens of papers on topics related to the treatment of a broad array of conditions crossing multiple therapeutic categories, as well as health risk assessments and drug safety evaluation. A list of my publications is included as part of **Exhibit 1**.

D. Compensation

I am being compensated for my time expended in connection with this case at the rate of $650 per hour, plus expenses. I have been assisted in this matter by staff of Innovative Science Solutions, Inc. who worked under my direction. My compensation is in no way dependent or based on the outcome of this matter, the outcome of any issues in this matter, or the timing of when issues in this matter or this matter as a whole are resolved.

III. OPINIONS

A. FDA Regulation of Dietary Supplements

The dietary supplement industry is regulated at the federal level by the Food and Drug Administration ("FDA") and the Federal Trade Commission ("FTC"). FDA and FTC regulations cover, *inter alia*, dietary supplement safety, manufacturing, labeling, and marketing.

The FDA's authority derives from the Federal Food, Drug and Cosmetic Act (FD&C Act), which, among other things, directs the FDA to "protect the public health by ensuring that . . . foods are safe."[1]

B. Generally Recognized as Safe (GRAS) Status

1. Statutory/Regulatory Background

The history of GRAS can be traced to 1906 when the Pure Food and Drug Act was passed; other important legislation in GRAS history includes the 1938 Federal Food Drug and Cosmetic Act, the 1958 Food Additives Amendment and 1958 GRAS list. The purpose of the Food Additives Amendment was "(1) [t]o protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels."[2] Under the 1958 Food Additives Amendment, any substance intentionally added to food is considered a "food additive" and must undergo premarket approval by the FDA, subject to certain exemptions.[3] Among the substances exempt from regulation as food additives are food ingredients found by qualified experts to be "generally recognized as safe" (GRAS) for their intended use based on scientific procedures or common use in food prior to 1958.[4]

Procedurally, the FD&C Act does not require FDA to conduct a premarket review of whether the use of a substance is GRAS. However, the statute and implementing regulations do require that a GRAS conclusion be based on the opinions of "experts qualified by scientific

[1] 21 U.S.C. § 393(b)(2).
[2] H.R. REP. NO. 85-2284, at 1 (1958).
[3] *See* 21 U.S.C. 321(s).
[4] *Id.*

training."[5] A GRAS assessment based on scientific procedures requires the "same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation," but it must "ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information."[6]

By 1972, the GRAS affirmation process began, which included a mechanism whereby a manufacturer or distributor could petition the FDA to review the GRAS status of a dietary ingredient not considered as part of the agency's review of "presumed" GRAS substances.[7] Under a final FDA Rule issued in 2016, and under prior draft guidelines, the FDA allows companies to have a substance obtain GRAS status by submitting a dossier of historical and scientific evidence of safety to an independent panel of experts and having that panel find the substance to be GRAS.[8] An ingredient is eligible for GRAS status based on expert recognition (via scientific procedures or experience) and scientific data, information, or methods, which ordinarily are published, and that may be corroborated with unpublished scientific data, information, or methods.[9] It is good practice that at least some of the supporting data are the sponsor's own data.

2. GRAS Process

Unless a substance has been in use before 1958, and thus GRAS can be determined by experience of use, GRAS is determined based on widely known scientific data and information,

[5] *Id.*
[6] *Id.*; 21 C.F.R. § 170.30(c)(1).
[7] FDA's Approach to the GRAS Provision: A History of Processes. (Jan. 2018). Available at: https://www.fda.gov/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes.
[8] Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016) (codified at 21 C.F.R. pts. 20, 25, 170, 184, 186 & 570).
[9] *Id.*

and there must be a consensus among qualified experts that those data establish the safety of the substance under the conditions of its intended use.[10] According to FDA guidance on GRAS:[11]

> Fundamental to all GRAS conclusions is the criterion that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use.

The requirements to establish GRAS include: (1) critical data and information relied upon to establish safety must be generally available (*i.e.*, primary or secondary scientific literature; opinion or recommendation of an authoritative body); and (2) consensus among qualified experts about the safety of the substance for its intended use (*i.e.*, "the expert panel").

The GRAS expert panel is comprised of unbiased, qualified experts who independently evaluate whether the available scientific data, information, and methods establish that an ingredient is safe under the conditions of its intended use.[12] The GRAS expert panel is considered a "proxy" for the larger scientific community.[13] The manufacturer or distributor relies on the outcome of the GRAS panel's analysis to support the conclusion that the safety of the intended use is "generally recognized" by qualified experts.[14] Any significant omission of any required discipline on the panel could compromise the quality of the committee's analysis, even if the committee is composed of highly qualified individuals.[15]

That GRAS expert panel finding can then be voluntarily submitted to the FDA ("Notified GRAS"), or the company can choose not to submit the GRAS finding to the FDA ("Self-

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[10] 21 C.F.R. § 170.30(a)
[11] Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry, FDA (Nov. 2017). Available at: https://www.fda.gov/media/109117/download.
[12] Best Practices for Convening a GRAS Panel: Draft Guidance for Industry, FDA (Nov. 2017). Available at: https://www.fda.gov/media/109006/download.
[13] *Id.*
[14] *Id.*
[15] *Id.*

Affirmed GRAS"). Self-Affirmed GRAS status *should* be of the same scientific rigor as a GRAS notification submitted to the FDA. Manufacturers are responsible for complying with the law, and the FDA has made clear that they need to be able to support their GRAS conclusions with objective scientific evidence.[16]

Furthermore, supporting safety data for a GRAS determination must be publicly available.[17] Therefore, if a sponsor decides that the GRAS conclusion will not be submitted to the FDA, the basis for the independent GRAS conclusion should be made publicly available by placing a document analogous to the GRAS notice and/or a report of any GRAS panel on the sponsor's website.[18]

When FDA receives a GRAS notice, it evaluates whether the submitted notice is sufficient for a GRAS determination or whether the information in the notice (or otherwise available) raises potential questions on whether the substance is indeed GRAS.[19] The FDA can respond without question to the GRAS conclusion (by issuing a "no objection" letter) or the agency may conclude the notice does not provide sufficient evidence of a GRAS conclusion.[20]

C. New Dietary Ingredients Notifications

1. New Dietary Ingredients

A new dietary ingredient (NDI) is defined as "a dietary ingredient that was not marketed in the United States before October 15, 1994."[21] Dietary ingredients marketed prior to October

[16] 81 Fed. Reg. at 55,028.
[17] 81 Fed. Reg. at 54,973 ("Regardless of whether the data and information are published or unpublished . . . a GRAS conclusion must be based on data and information that are generally available and accepted, and as such, are publicly available.").
[18] *Id.*
[19] About the GRAS Notification Program, FDA (Jan. 2018). Available at: https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program.
[20] *Id.*
[21] 21 U.S.C. § 350b(c).

15, 1994 (referred to in the industry as "old dietary ingredients") are not NDIs.[22] Under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, must submit a premarket safety notification (an "NDI Notification" or "NDIN") to the FDA at least 75 days before introducing the product to market, unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered."[23] From a public health perspective, NDI notifications ensure that consumers are not exposed to potential health risks in the form of an NDI with an unknown safety profile.[24]

2. NDI Notifications

In September 1997, the FDA published a final rule establishing regulations that a manufacturer or distributor must follow when submitting an NDIN.[25] The notification "must contain the information, including any citation to published articles, which provides the basis on which the manufacturer or distributor of the NDI or dietary supplement (the "notifier") has concluded that the dietary supplement containing the NDI will reasonably be expected to be safe."[26] This includes evidence of history of safe use, clinical studies, and/or animal studies.[27]

[22] The use of an ingredient in conventional foods prior to October 15, 1994 does not determine whether the ingredient is an NDI. *See* Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry, FDA (Aug. 2016), available at: https://www.fda.gov/media/99538/download. Only an ingredient that was marketed in, as, or for a dietary supplement in the U.S. before October 15, 1994 falls outside of the NDI classification. *Id.*
[23] 21 U.S.C. 350b(a)(2).
[24] Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry, FDA (Aug. 2016). Available at: https://www.fda.gov/media/99538/download
[25] 21 CFR §190.6
[26] 21 U.S.C. 350b(a)(2).
[27] Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry, FDA (Aug. 2016). Available at: https://www.fda.gov/media/99538/download.

Thus, any ingredient with safety concerns would not be acknowledged without objection by the FDA following review.

Generally, the following information is included in the NDIN:

- Description of the identify and composition of the NDI and dietary supplement in which the NDI will be marketed;
- The basis for the conclusion the ingredient is an NDI;
- Conditions of use recommended or suggested in the labeling;
- History of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will be reasonably be expected to be safe;
- A comprehensive safety profile with summaries of all available human and animal data, and any other information relevant to the safety of the NDI; and
- A safety profile substantiating the safety of the NDI in humans under the proposed conditions of use described in the notification.

The notifier is responsible for determining what information provides the basis for the conclusion of safety. Nevertheless, the FDA recommends that **at minimum** the notifier conduct a comprehensive search of the scientific literature and consider the evidence of safety for the ingredient, including adverse events.[28]

If the required premarket notification is not submitted to FDA at least 75 days before introducing it into interstate commerce, a dietary supplement containing the NDI is deemed "adulterated" (*i.e.*, lacking in adequate information to provide reasonable assurance of safety).[29] Sections 302 and 304 of the FD&C Act provide for seizure of violative products and injunctions against the manufacturers and distributors of violative products.[30]

[28] New Dietary Ingredients in Dietary Supplements - Background for Industry. (2020). Available at: https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry.
[29] 21 U.S.C. § 350b; 21 U.S.C. § 342(f).
[30] 21 U.S.C. §§ 332 and 334.

3. FDA's Review of NDINs

A complete NDIN contains all the information required by 21 C.F.R. 190.6. The date of filing starts the 75-day premarket review period during which the manufacturer or distributor of a dietary supplement containing an NDI(s) may not market the dietary supplement. During review of the notification, the FDA may request submission of raw data or other additional information. If the notification does not meet the requirements, a member of the FDA's Office of Dietary Supplement Programs will contact the notifier to determine how long it will take to provide the missing information.[31]

Within 75 days, the notifier can expect a letter acknowledging receipt of the NDIN. There are several types of response letters that can be expected:[10]

- Letter of acknowledgment "without objection;"
- Letter listing deficiencies that make the notification incomplete;
- Objection letter that raises safety concerns based on information in the notification or gaps in the history of use or other safety evidence;
- Letter raising other regulatory issues with the NDI or dietary supplement (*e.g.*, the subject of the notification is not a dietary ingredient/supplement).

In November of 2020, through a Freedom of Information Act request, Natural Products Insider obtained an FDA spreadsheet tallying the number of NDINs submitted and FDA responses by category.[32] Of the 1,078 substantive FDA responses since 1995, only 288 have been letters acknowledging an NDIN without objection, compared with nearly 800 letters from the FDA objecting to notifications due to safety or other concerns.[33]

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[31] Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry (2011). Available at: https://www.fda.gov/media/99538/download

[32] "26 years post-DSHEA, FDA still rejects most NDI notifications." Natural Products Insider (2020). Available at: https://www.naturalproductsinsider.com/regulatory/26-years-post-dshea-fda-still-rejects-most-ndi-notifications.

[33] *Id.*

D. Improper Reliance on Prior NDINs or GRAS Assessments

A company may not just rely on an existing GRAS assessment or NDIN for its own product. With respect to NDINs, except in limited circumstances, dietary supplement manufacturers or distributors must submit separate notifications for each supplement that contains an NDI and cannot rely on a previously-submitted notification from a different manufacturer or distributor. The FDA has made clear that each manufacturer or distributer of a dietary supplement that contains an NDI must comply with the NDI Notification requirement.[34] Additionally, a new NDI notification is warranted if a dietary supplement combines a previously-notified NDI with another active ingredient.[35]

Likewise, any changes to the manufacturing process that alter the identity of the ingredient will convert a previously marketed dietary ingredient into an NDI. Manufacturing changes that alter the physicochemical structure or properties, purity and impurities, or biological properties of the ingredient also result in an NDI.

Finally, according to the FDA *Draft Guidance for Industry: New Dietary Ingredient Notifications and Related Issues*[36], a sponsor submitting its own NDI may only rely on data from another NDI notification if:

- That sponsor submitted the previous notification or master file; or
- The previous notification the sponsor wishes to rely upon is public; or
- The person who submitted the previous notification gives written permission to rely on non-public information from that notification, and the sponsor should provide the FDA with documentation showing that they are authorized to use the information.

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[34] Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: FDA, Draft Guidance for Industry, FDA (Aug. 2016) ("[E]ach manufacturer or distributor of a supplement containing the NDI must submit an NDI notification . . . .").
[35] *Id.*
[36] *Id.*

If the above criteria are not met, the sponsor cannot rely on data from a previous notification and a new NDIN is warranted.

With respect to GRAS, according to 21 C.F.R. 570.30, new information may result in reconsideration of GRAS status. For example, a significant manufacturing process change to a food substance already in the market can affect the identity, profile, or conditions of use of that food substance, thus the properties of the dietary ingredient may not match the information considered in a determination of GRAS status, rendering the previous assessment of GRAS status inapplicable. The FDA recommends that whenever there has been a significant manufacturing process change, the manufacturer or distributor:[37]

- Determine what changes have been made to the identity of the substance as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Conduct a safety assessment, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, and/or toxicity;
- Consider whether the use of the substance is within the scope of GRAS identification.

E. Current Good Manufacturing Practice (cGMP)

Current Good Manufacturing Practice (cGMP) are regulations enforced by the FDA that help ensure the safety and efficacy of dietary supplement products through proper manufacturing, packaging, and labeling. The minimum cGMPs required for manufacturing, packaging, labeling, or holding dietary supplements are set forth in 21 CFR Part 111. The cGMPs applicable to human food are set forth in 21 CFR Part 117 (and previously in 21 CF Part 110).

[37] Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives, FDA (2014). Available at: https://www.fda.gov/media/115075/download

Every step of the manufacturing process should meet the requirements of the current Good Manufacturing Practice (cGMP) regulations. If a company does not comply with cGMP regulations, any product that it produces is considered "adulterated" under the law and considered potentially unsafe.[38]

Per 21 CFR Part 111, the FDA has established a cGMP regulation as part of the "Dietary Supplement Current Good Manufacturing Practice (CGMP) Final Rule" that addresses manufacturing processes for dietary supplements and the accurate listing of supplement ingredients. Specific to dietary supplements, the FDA requires:[39]

- "certain activities in manufacturing, packaging, labeling and holding of dietary supplements to ensure that a dietary supplement contains what it is labeled to contain and is not contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities.
- Requires certain activities that will ensure the identity, purity, quality, strength, and composition of dietary supplements, which is a significant step in assuring consumers they are purchasing the type and amount of ingredients declared."

In 2020, ConsumerLab obtained the results from the FDA's inspections in Fiscal Year 2019 (October 1, 2018 - September 30, 2019) of 598 dietary supplement manufacturing facilities in the U.S. and abroad. Among U.S. facilities that were inspected in 2019, 52% received citations for GMP noncompliance. Among international facilities that were inspected in 2019, 41.7% received noncompliance citations. Of the international facilities, China had six

[38] Facts About the Current Good Manufacturing Practices (CGMPs). (2018). Available at: https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps

[39] Backgrounder on the Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements. (2007). Available at: https://www.fda.gov/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/backgrounder-final-rule-current-good-manufacturing-practices-cgmps-dietary-supplements

inspections in 2019, with 50% receiving noncompliance citations; according to ConsumerLab, this number is down from 71.4% receiving citations in 2016.[40]

F. ChromaDex's Product: NIAGEN®

ChromaDex is a publicly traded nutraceutical company founded in 1999. One of the products that ChromaDex makes and sells is NIAGEN®, a patented and proprietary health ingredient that is comprised of NR. NR is a form of vitamin B_3, and a precursor to nicotinamide adenide dinucleotide (NAD+), an essential molecule found in every living cell. ChromaDex also markets a dietary supplement directly to consumers called TRU NIAGEN®.

1. ChromaDex's successful GRAS notification

In August 2016, NIAGEN® was successfully GRAS notified (GRN No. 635) to the FDA.[41] As described above, to achieve GRAS status, the scientific data related to the use of an ingredient must be "widely known and there must be a consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use." ChromaDex submitted a thorough safety package that included, among other things: information on identity and composition; a detailed description of the manufacturing process; production specifications (including for color, purity, residual solvents, reaction by-products, and heavy metals); and batch analysis results and stability data for multiple batches of NIAGEN®. ChromaDex's safety package additionally included published study results from a clinical pharmokinetic study in humans,[42] a genotoxicology battery (including Ames assay, *in vitro*

[40] ConsumerLab. FDA Finds Problems at 52% of Supplement Manufacturing Sites in U.S. and 42% Abroad. (2020). Available at: https://www.consumerlab.com/recalls/14344/fda-finds-problems-at-52-of-supplement-manufacturing-sites-in-us-and-42-abroad/.

[41] E_SDNY00018289-388 (GRAS Dossier).

[42] Conze D, Crespo-Barreto J, Kruger CL. 2016. Safety Assessment of Nicotinamide Riboside, a Form of Vitamin B3. Human & Experimental Toxicology, January. doi:10.1177/0960327115626254.

chromosome aberration assay, and *in vivo* micronucleus assay),[43] and a 90-day toxicology study in rats.[44]

An independent panel of experts in toxicology evaluated the data and information in ChromaDex's dossier and determined that NIAGEN® is safe for its intended conditions of use based on several considerations, including the following:[45]

- The product is manufactured in a facility that complies with cGMP for foods;
- Finished product batches reproducibly meet compositional standards and comply with limits on contaminants;
- All processing aids used in the production are determined GRAS for their use and/or comply with regulations set forth in 21 C.F.R. § 110 for use in food;
- Specifications are set for the final product to comply with appropriate controls on residual solvents and other processing aids for food;
- No clinically adverse effects on hematology, clinical chemistry, urinalysis, or liver or kidney function parameters in humans at 100, 300 and 1000 mg doses.;
- Published *in vitro* chromosome aberration assay and *in vivo* micronucleus assay demonstrating that NIAGEN® is not genotoxic;
- A published 90-day rodent toxicology study demonstrating a no-observed-adverse-effect level (NOAEL) of 300 mg/kg/day for NIAGEN®;
- NOAEL results in an upper limit of 3 mg/kg/day or 180 mg/day for a 60 kg individual.

The expert panel concluded:[46]

> There is no evidence in the information reviewed on Niagen that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when this product is used at levels that might reasonably be expected from the proposed applications. Niagen is GRAS for use in foods and beverages as proposed by ChromaDex, Inc.

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[43] Trammell SAJ, Schmidt MS, Weidemann BJ, Redpath P, Jaksch F, Dellinger RW, Li Z, Abel ED, Migaud ME, Brenner C. 2016. Nicotinamide Riboside Is Uniquely and Orally Bioavailable in Mice and Humans. Nature Communications 7 (October 2016): 12948. doi:10.1038/ncomms12948.
[44] *Id.*
[45] E_SDNY00018289-388 (GRAS Dossier).
[46] *Id.*

ChromaDex submitted the GRAS dossier and expert panel statement to the FDA on March 8, 2016.[47] The FDA provided ChromaDex with a letter dated August 3, 2016, stating that the FDA had "no questions at this time regarding ChromaDex's conclusion that NR is GRAS under the intended conditions of use."

Thus, ChromaDex established the safety of NIAGEN® using the standard regulatory pathway. It is my opinion that ChromaDex had a rigorous regulatory submission package for the NIAGEN® GRAS determination.[48]

2. ChromaDex's Successful NDINs

NIAGEN® was successfully reviewed twice under the FDA's NDIN program, in November 2015 (180 mg/day, NDIN 862)[49] and again in March 2018 (300 mg/day, NDIN 1062).[50] ChromaDex's notifications set forth the technical and manufacturing details of NIAGEN®, stability data, and detailed information on NIAGEN®'s stability specifications (including defining the purity specification for NIAGEN®, and the impurities, residual solvents and contaminants that may be present within defined limits). ChromaDex additionally included with its dossiers certificates of analysis, analytical methods, and standard operating procedures. The notifications specify that the intended use is as a sole active ingredient in a dietary supplement capsule formulation.

In its NDIN dossiers, ChromaDex also provided a comprehensive safety testing package, including multiple genetic toxicity studies, 14-day dose range finding in rodents and 7-day dose range finding in dogs, 90-day sub-chronic oral study in rodents, single and chronic dose

[47] *Id.*
[48] *Id.*
[49] CDXCA_00323954-00324036 (NDIN 862)
[50] CDXCA_00097979-00098055 (NDIN 1062)

tolerability in humans, one generation rodent reproductive study, and developmental toxicity in rodents.

Pivotal toxicology studies demonstrated the general safety of NIAGEN®. These studies included mutagenicity, acute toxicity (rodent), and 90-day subchronic toxicity (rodent). Specifically, the 90-day subchronic study revealed that NIAGEN® at 300 mg/kg/day did not result in treatment-related adverse effects and was considered the no-observed-adverse-effect level NOAEL. Two studies conducted in juvenile dogs also confirmed a lack of adverse effects on safety pharmacology endpoints.[49]

By the second NDI notification, submitted in 2017, ChromaDex had completed four long-term clinical trials to support the safety NIAGEN®. Notably, in two clinical studies, it was shown that NIAGEN® (300 mg) did not cause any clinically relevant changes in white blood cell count.[51] [52] [53] Based on the data provided in ChromaDex's NDINs, it is my opinion that ChromaDex had rigorous regulatory submission packages for both NDINs.

The FDA acknowledged both NDINs without objection.[54]

Notably, as shown by the Natural Products Insider's FDA spreadsheet discussed above, in the years that NIAGEN® was reviewed, there were more objection letters than AKL responses. In 2015, only 10 NDINs received AKL responses, whereas there were 25 objection letters. Likewise, in 2018, 17 NDINs received AKL responses, whereas there were 21 objection letters. These statistics demonstrate that the FDA objects to the majority of NDINs. Had there

[51] New Dietary Ingredient Notification For Niagen (Nicotinamide Riboside Chloride), December 27, 2017 at p. 3;
[52] Airhart, S.E., et al., An open-label, non-randomized study of the pharmacokinetics of the nutritional supplement nicotinamide riboside (NR) and its effects on blood NAD+ levels in healthy volunteers. PLoS One, 2017. 12(12): p. e0186459.
[53] Dollerup, O.L., et al., A randomized placebo-controlled clinical trial of nicotinamide riboside in obese men: safety, insulin-sensitivity, and lipid-mobilizing effects. Am J Clin Nutr, 2018.
[54] *See* Dkt. No. 80-1 and CDXCA_0022956-957.

been safety concerns related to NIAGEN®, the FDA would not have issued letters of acknowledgment "without objection" to the NDINs.

G. Elysium's Product: Basis

Elysium sells a product, Basis, for human consumption. Basis combines NR with pterostilbene (PT), a polyphenol related to resveratrol. Elysium instructs consumers to take two Basis capsules twice per day. A daily dose of Basis contains two active ingredients: 250 milligrams of NR and 50 milligrams of PT.

When Elysium launched Basis in February 2015, it sourced both NR and PT exclusively from ChromaDex. Elysium's last orders for NR and PT from ChromaDex were placed on June 30, 2016. Since that time, Elysium has utilized at least five different manufacturers for its NR and at two different manufacturers for its PT.[55]

Elysium's Chief Product Officer, Mark Morris—who was the designated corporate representative under FRCP 30(b)(6) for topics related to GRAS and NDIN—confirmed that Elysium has never submitted an NDIN for Basis or either of its ingredients (NR and PT).[56]

Elysium prepared a "GRAS Notification of Nicotinamide Riboside Chloride" dated October 27, 2017.[57] It prepared a "Comprehensive GRAS Assessment of Pterostilbene," dated February 2, 2018.[58] Mr. Morris testified that the Elysium's PT GRAS assessment was not reviewed by an independent panel.[59] Elysium did not submit either of its GRAS assessments to

[55] *See* Elysium's Supplemental Responses to ChromaDex's Interrogatories Nos. 2 and 4, dated October 30, 2020.
[56] Deposition of Mark Morris, February 4, 2021, page 108.
[57] E_SDNY00020578-647 (Elysium's "GRAS Notification of Nicotinamide Riboside Chloride").
[58] E_SDNY00071774-829 (Elysium's "Comprehensive Gras Assessment for Pterostilbene").
[59] Deposition of Mark Morris, February 4, 2021, page 125, 129.

the FDA.[60] According to Mr. Morris, this was a "[b]usiness decision [that] was taken for efficiency, proper utilization of resources[,] . . . human resources, financial resources, timing."[61]

H. Elysium's Representations Regarding Basis

In its Second Amended Complaint, ChromaDex alleges that Elysium makes several false or misleading representations regarding Basis, including about the product's safety, purity, and regulatory status. The following are examples of allegedly false or misleading representations:

- A section on Elysium's website titled, "Common Question," followed by: "We answer your most common questions about Basis, from the ingredients in each capsule to compliance with FDA regulations." One of the questions is: "Does Basis comply with FDA recommendations?" followed by the corresponding answer stating: "The ingredients in Basis have been tested for safety and are produced in facilities that meet FDA requirements. Basis also undergoes rigorous third party purity and quality testing."

- A section on the "Mission" page of the Elysium website, titled "How We Work: Our R&D Process," under which it states "[o]ur process for all products begins with a comprehensive evaluation of all available scientific literature and culminates in a product becoming available for purchase. In between there are many important steps. The steps below help us discover and commercialize new products. They don't all necessarily happen in this order." The "steps" that follow are: "Review Literature;" "Preclinical Development;" "FDA NDI Submission;" "Safety Testing;" and "Efficacy Testing." Next to "FDA NDI Submission," the website states the following: "We conduct rigorous safety studies for a new dietary ingredient (NDI) submission to the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of "new dietary ingredients."

- A statement on the "Mission" page of Elysium's website stating: "Elysium states that "All manufacturing facilities are located in the US and are compliant with the cGMP regulations as stipulated by the FDA."

- A statement on Elysium's website that: "Both primary ingredients in Basis are GRAS (generally recognized as safe) under intended conditions of use by qualified experts."

- A statement on Elysium's website, under the heading "Exceeds FDA Recommendations," that: "The ingredients in Basis have been tested for safety and

[60] Deposition of Mark Morris, February 4, 2021, page 107.
[61] Deposition of Mark Morris, February 4, 2021, page 107, 114.

are produced in facilities that meet FDA requirements. Basis also undergoes rigorous third party purity testing."

- Representations made to journalists that Basis is GRAS.

I. Regulatory Status of Basis

1. Elysium's "GRAS Notification" for NR

In its October 2017 "GRAS Notification" for NR, Elysium relies on ChromaDex's data in all substantive aspects, for example, repeatedly referring to the existing GRAS status of NIAGEN® (p. 12), ChromaDex's stability studies (p. 16), ChromaDex's clinical studies (p. 33), and ChromaDex's pharmacokinetic study (p. 38).[62] In fact, the crux of the Elysium's GRAS assessment is that ChromaDex and the FDA have found NIAGEN® to be GRAS, therefore Elysium's new NR must be GRAS as well.

Based on my review, Elysium apparently relies on ChromaDex's data to establish the safety of its NR. In my experience, this is highly unusual. It is inappropriate for Elysium to claim that the NR in Basis "enjoys Generally Recognized as Safe status"[63] based upon NIAGEN's GRAS status.

As discussed above, at any time, new information may result in reconsideration of GRAS status. A significant manufacturing change can affect the identity or conditions of use of a food substance; thus, the properties may not match the information considered in a prior GRAS assessment, rendering the previous determination of GRAS status inapplicable. GRAS conclusions can only apply to ingredients from other companies if the ingredients are manufactured in a way that is consistent with the existing notification and they meet the listed specifications.[64]

[62] E_SDNY00031517-86 (Elysium's "GRAS Notification" for NR).
[63] Third Amendment Counterclaims. p. 10.
[64] 21 C.F.R 570.30.

Relevant to this case, in their GRAS assessment, Elysium included a chart comparing the specifications for Elysium's NR and ChromaDex's NR, which demonstrates important differences in the specifications, solvents, by-products (including acetamide), and impurity specifications: [65]

Physical and Chemical Parameters	Elysium's Specifications for NR	Chromadex's Specifications for NR
Appearance, Form & Color	[redacted]	White to light brown
Identification		Conforms to structure by NMR
Loss on Drying		N.S.
Water Content		≤ 0.1%
Purity/Assay		95-102% by weight
Residual Solvents		
Acetonitrile		Not detected (LOD 6 ppm)
Acetone		≤ 3000 ppm
1,4-Dioxane		N.S.
Ethanol		N.S.
Isopropanol		N.S.
Methanol		≤740 ppm
MTBE		Not detected (LOD 4 ppm)

[65] E_SDNY00071774-829 (Elysium's "Comprehensive Gras Assessment" for Pterostilbene).

Physical and Chemical Parameters	Elysium's Specifications for NR	Chromadex's Specifications for NR
Tributylamine	[redacted]	N.S.
Potential By-Products		
Methyl acetate		Not detected (Below LOQ 15 ppm)
Acetamide		Not detected (Below 25 LOQ ppm)
Acetic Acid		≤5000 ppm
Impurities		
Nicotinamide		N.S.
Nicotinamide riboside triacetate		N.S.
Ribofuranose tetraacetate		N.S.
Heavy Metals		
Lead		≤ 0.5 ppm
Arsenic		≤ 1 ppm
Cadmium		≤ 1 ppm
Mercury		≤ 1 ppm
Microbiological Limits		
Total Plate Count		≤ 1000 CFU/g
Total Yeast and Mold		≤ 100 CFU/g
E. coli		Absent in 25 g
Staphylococcus aureus		N.S.
Pseudomonas aeruginosa		N.S.
Salmonella		N.S.

Thus, Elysium could and should not have relied upon the NIAGEN® GRAS assessment for assurance of safety given the differences in specifications and impurity profiles.

It should also be noted that in its counterclaims, Elysium asserts that its NR has been "extensively tested for safety,"[66] while also claiming a lack of rigorous safety testing on the part of ChromaDex. Yet, it is ChromaDex data and publications that Elysium relied upon to support its GRAS assessment.

Importantly, despite its title, Elysium's GRAS "Notification" for NR was never submitted to the FDA. If a sponsor decides that its GRAS conclusion will not be submitted to the FDA, the basis for the GRAS conclusion should be made publicly available by placing a document analogous to the GRAS notice and/or a report of any GRAS panel on the sponsor's website. I have reviewed Elysium's website and it does not appear as if its GRAS assessment of NR was made publicly available.

2. Elysium's purported self-affirmed GRAS conclusion for its PT was not expert panel reviewed

In its February 2018 "Comprehensive GRAS Assessment of Pterostilbene," Elysium concluded that its PT is "generally recognized as safe in foods at the usage levels."[67] However, a chart in the Elysium GRAS document indicated that several impurities found in Elysium's PT exceeded the maximum daily exposure limit. Yet, Elysium considered the elevated levels to be "no safety concern."

It is also noted, although this was intended as a GRAS assessment for PT, only one of the four relied upon human studies examined PT alone; the other three studies evaluated PT in another extract or in combination with other ingredients, and one of these studies did not discuss

[66] Third Amendment Counterclaims. p. 49

[67] E_SDNY00071774-829 (Elysium's "Comprehensive Gras Assessment" for Pterostilbene), at p. 27.

adverse reactions.[68] Additionally, in the summary provided for Dellinger et al., 2017 (an Elysium-sponsored study),[69] five adverse events were attributed to the combination of NR *with PT*, yet there is no discussion of what those adverse events were.

As with its GRAS assessment for NR, Elysium never submitted its GRAS assessment for PT to the FDA. Elysium's GRAS assessment of PT was not even reviewed by an expert panel.[70] I have reviewed Elysium's website and it does not appear as if its GRAS assessment for PT determination has been made publicly available.

3. Subsequent manufacturer changes

Elysium claims that its NR and PT are GRAS based on the above-discussed October 27, 2017 and February 2, 2018 GRAS assessments for NR and PT, respectively. Even assuming that to be true as of the date of as of the GRAS assessment dates, as noted above, changes to Elysium's manufacturers, specifications, and purity profiles may necessitate new assessments.

4. Basis is not covered by ChromaDex's NDINs

ChromaDex's successful NDI notifications for NIAGEN® are based on the characteristics and intended use specified therein. Most notably, the notifications specified the intended use for NIAGEN® is as the sole active ingredient in a dietary supplement capsule, whereas Elysium combines its NR with PT in Basis. ChromaDex's NDINs did not examine the safety of NR+PT. In order to avail itself of the regulatory pathway for New Dietary Ingredients, Elysium would have to submit its own NDIN providing information demonstrating a reasonable expectation of safety based on the characteristics of its NR when combined with PT in Basis.

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[68] E_SDNY00071774-829 (Elysium's "Comprehensive Gras Assessment" for Pterostilbene).
[69] Dellinger RW, Santos SR, Morris M, Evans M, Alminana D, Guarente L, Marcotulli E. Repeat dose NRPT (nicotinamide riboside and pterostilbene) increases NAD+ levels in humans safely and sustainably: a randomized, double-blind, placebo-controlled study. NPJ Aging Mech Dis. 2017 Nov 24; 3: 17.
[70] E_SDNY00071774-829 (Elysium's "Comprehensive Gras Assessment" for Pterostilbene).

5. Elysium's cGMP compliance

Elysium asserts that its NR and PT are manufactured in compliance with current good manufacturing practices (cGMP) for foods. However, it is my understanding that Elysium has had multiple manufacturing changes in China. While the requirements of China GMP standards are somewhat similar to United States GMP standards, there are some important differences. For example, China GMP standards do not have requirements for process validation, nor do they require that abnormal (*i.e.*, "out of specification") test results be investigated or even recorded.[71] Moreover, Elysium did not conduct an inspection of its Chinese manufacturers' facilities to ensure cGMP compliance.[72] Thus, even assuming that each of the facilities that Elysium employed met GMP standards appropriate for China, they likely did not meet GMP standards appropriate for the United States. There is also no evidence that Elysium performed physical inspections of the facilities for any of its manufacturers based outside of the United States. Based upon my understanding of GMP standards, for Elysium to assert that their NR is manufactured in a facility that is GMP compliant may be misleading.

[71] BioProcess International. Good Manufacturing Practice in China: Equipment Strategy and Quality Management to Compete with the West. Available at: https://bioprocessintl.com/business/regulatory-affairs/good-manufacturing-practice-in-china-equipment-strategy-and-quality-management-to-compete-with-the-west/

[72] Deposition of Ramon Padilla, February 2, 2021, pages 70-81.

EXHIBIT 1

TO

EXPERT REPORT OF DR. STEVEN M. WEISMAN

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STEVEN M. WEISMAN, Ph.D.

EDUCATION

1986	Postdoctoral Fellow, Immunopharmacology, Roche Institute of Molecular Biology, Nutley, NJ
1986	Ph.D., Pharmacology, Cornell University School of Medicine, New York, NY
1981	B.S., Biology, Fairleigh Dickinson University, Madison, NJ

EXPERIENCE

Dr. Weisman is President and Chief Executive Officer at Innovative Science Solutions, providing consulting services to industry and counsel on regulated healthcare products. He has over 20 years of experience in pharmacology, toxicology, pharmaceutical product development, and marketing evaluation and communication. Previously, Dr. Weisman was Global Director of Medical and Clinical Affairs at Bayer Corporation. Prior to joining Bayer, he was the Director of Strategic Research at Sterling Winthrop Inc. He has also held positions of responsibility with Hoffmann La Roche and Procter & Gamble.

Dr. Weisman has extensive experience in developing regulatory strategies, product development plans, preclinical and clinical testing programs, regulatory submissions, and product defense/ communication strategies for drugs, foods, cosmetics, and dietary supplements. He has organized and presented at numerous symposia, FDA Advisory Panel and other regulatory meetings. His skills in analyzing the scientific and regulatory aspects of potential new products and the development of responses to FDA Rule-Makings are sought by numerous clients.

Dr. Weisman has been responsible for Investigational New Drug applications (INDs), New Drug Applications (NDAs), and other regulatory filings, managed clinical research efforts, and designed adverse event tracking systems. He is also an authority on developing new indications and claims for mature brands, and in crisis and media relations. In addition, he has extensive experience in global product development and communication strategies.
Representative examples of Dr. Weisman's experience include:

Strategic and Regulatory Support to the Nonprescription Drug, Cosmetic and Dietary Supplement Industries

- Provided ongoing scientific and strategic support to clients in resolving safety and effectiveness issues.

- Designed and implemented regulatory strategy and product development plans, preclinical/clinical testing programs for new and existing products.

- Developed claim substantiation programs for dietary supplement products.
- Presented clinical data at numerous regulatory hearings.
- Managed the preparation of INDs, NDAs and petitions for products with a variety of applications.
- Managed the R_x-to-OTC switch process.
- Developed communications programs to deal with safety and efficacy issues.
- Developed public policy influence programs to ensure rapid regulatory approval of new indications and labeling.
- Designed and implemented FDA Advisory Panel presentations for clients in support of new and existing products.
- Testified in support of ingredients before the Cosmetic Ingredient Review.

Drug Development and Regulatory Support

- Directed and/or contributed to the preparation of product development plans, IND submissions, NDAs, design of preclinical testing regimens, and clinical trial design and analysis for a variety of compounds including anti-inflammatory, gastrointestinal cardiovascular, analgesic, respiratory, neurology, obesity, antiviral and psychoactive products.
- Developed formulation development strategies.
- Directed due diligence evaluations of potential product acquisitions for regulatory, scientific, and marketing issues.
- Contributed to and directed the evaluation of scientific and regulatory issues for novel new products.
- Conducted clinical trials (Phases I through IV) for analgesic, cardiovascular, neurologic, dermatologic, and other therapeutic categories.

Litigation Support and Advice to Counsel

- Provided product defense efforts for product liability and class action suits. Activities included litigation support (including expert witness identification and development), and critical analysis of relevant literature.
- Provided expert witness testimony in numerous legal matters.

- Prepared critical overviews of the scientific literature for issues under review by the National Advertising Division (NAD) of the Better Business Bureau, the Federal Trade Commission (FTC), and U.S. Food and Drug Administration (FDA).

- Developed sworn affidavits on technical issues relevant to patent defense and advertising issues.

Marketing Support/New Business Opportunities

- Developed sales aids/technical training programs and slide lecture sets.

- Developed pharmacoeconomic support for new and existing products.

- Directed medical education programs, including advisory committees, publication strategies, and publication management.

- Developed substantiation for advertising programs and matters before the NAD, FTC, and FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC).

- Developed technical competitive intelligence programs across a number of therapeutic categories.

- Conducted due diligence assessment of acquisition candidates.

- Developed managed care strategies for new and existing products.

Communication Support

- Developed scientific public and media relations strategies to enhance marketing efforts as well as regulatory and legislative initiatives.

- Trained spokesperson in media response to technical issues.

- Acted as product spokesperson on scientific matters, including on camera.

- Assisted clients in scientific matters before state and federal agencies

EMPLOYMENT

Innovative Science Solutions, Inc., President and Chief Executive Officer

Dr. Weisman's diverse scientific consulting experiences focuses on the regulatory and clinical evaluation of a variety of therapeutic compounds and on communicating benefits to consumers, health care professionals, regulatory and legislative policy makers.

Bayer Corporation, Consumer Care Division. **Director, Medical and Clinical Affairs**

Responsible for ensuring the safe and effective use of Bayer products and all aspects of medical management of drug development, clinical research, public relations, FDA interaction, adverse event tracking and reporting, and product identification and evaluation.

Sterling-Winthrop Inc., New York, NY. Director, Strategic Research, Consumer Health Group

Responsible for managing OTC drug development process from idea generation through commercialization for $1 billion OTC division. Managed preclinical, clinical research, and strategic regulatory affairs activities.

The Procter & Gamble Company, Cincinnati, OH. Manager, Immunopharmacology, Health and Personal Care Division

Managed pharmacology program for screening and evaluation of new drug compounds.

Hoffmann La Roche, Inc., Nutley, NJ. Research Associate, Allergy and Inflammation

Conducted research on the mechanism of action of novel compounds for the treatment of allergic and inflammatory disorders.

PUBLICATIONS

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Steven M. Weisman, Ph.D.
Summary of Expert Witness Testimony
(last updated February 18, 2021)

Case Name	Case No./Court	Case Closed Date	Testifying Dates
Federal Trade Commission v. Sunrise Nutraceuticals, LLC and Joshua Erickson	9:15-cv-81567-MIDDLEBROOKS/U.S.D.C. for the Southern District of Florida	7/8/16	
EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation – Consumer Class Cases	2:17-MD-2785-DDC-JJ		12/24/2019 (deposition)
ABSORPTION PHARMACEUTICALS, LLC, a Delaware limited liability company, Plaintiff, v. RECKITT BENCKISER, LLC, a Delaware limited liability company, and DOES 1-50, Defendants	2:17-cv-12872 (MCA) (JAD		
NOVAQUEST CO-INVESTMENT FUND II, L.P. Claimant v. PFIZER INC., Respondent	AAA Case No. 01-18-0003-8870		11/24/2020

EXHIBIT 2

TO

EXPERT REPORT OF DR. STEVEN M. WEISMAN

Material Considered for Dr. Steven M. Weisman Report

Pleadings

February 27, 2020 ChromaDex Second Amended Complaint and Exhibits (Dkt 139-139-34)

February 28, 2020 Elysium Third Amended Counterclaims and Exhibits (Dkt 141-141-10)

Produced Documents

November 3, 2015 NDIN 862 FDA Letter (Dkt. 80-1)

October 9, 2015 NDI 862 FDA Letter (CDXCA _00295360-00295361)

October 30, 2015 NDI 862 Notification - Amendment to FDA (CDXCA_00303355)

August 20, 2015 NDI 862 Notification (CDXCA_00323954-00324036)

October 12, 2015 NDI 862 ChromaDex Letter and Amendment (CDXCA_0037700 and CDXCA_00303355)

March 7, 2018 NDIN 1062 FDA Letter (CDXCA_0022956-0022957)

December 27, 2017 NDIN 1062 Dossier (CDXCA_00097979-00098055)

February 5, 2018 NDIN 1062 Dossier with updated specifications (CDXCA_00010088-00010161) March 8, 2016 GRAS 635 Notice (E_SDNY00018289-E_SDNY00018388)

August 3, 2016 GRAS 635 FDA Letter (Dkt. No. 80-2)

October 5, 2017 Addendum to GRAS 635 (CDX_00136783-00136842)

Elysium "GRAS Notification of Nicotinamide Riboside Chloride" (E_SDNY00020578-647 and E_SDNY00031517-86

Elysium "Comprehensive Gras Assessment for Pterostilbene" (E_SDNY00071774-829)

ChromaDex HCP Monograph (CDX_00094032-051)

Niagen Public Regulatory Approvals (CDX_00094052-053)

Publications

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Material Considered for Dr. Steven M. Weisman Report

Bieganowski P, et al. "Discoveries of nicotinamide riboside as a nutrient and conserved NRK genes establish a Preiss-Handler independent route to NAD+ in fungi and humans." Cell. 2004 May 14;117(4):495-502

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Dellinger RW, Santos SR, Morris M, Evans M, Alminana D, Guarente L, Marcotulli E. Repeat dose NRPT (nicotinamide riboside and pterostilbene) increases NAD+ levels in humans safely and sustainably: a randomized, double-blind, placebo-controlled study. NPJ Aging Mech Dis. 2017 Nov 24; 3: 17, plus supplemental tables

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Depositions and Related Exhibits

11-29-18 Shukla, Rajesh

11-28-18 Price, Edward S.

04-24-19 Morris, Mark

04-12-19 Jaksch, Frank

03-21-19 Padilla, Ramon

02-08-21 Kruger, Claire

02-05-21 Jaksch, Frank

02-04-21 Morris, Mark

02-02-21 Padilla, Ramon